IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent Number	:	7,741,080	Issue Date:	June 22, 2010
Application Number	:	10/594,969	Confirmation No.:	1288
Applicant	:	Takashi KADOWAKI, *et al.*		
Filed	:	September 29, 2006		
Title	:	ADIPONECTIN EXPRESSION-INDUCING AGENTS AND USES THEREOF		
TC/Art Unit	:	1647		
Examiner:	:	Elly Gerald STOICA		
Docket No.	:	68600.000002		
Customer No.	:	**21967**		

MAIL STOP PETITIONS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313–1450

RESPONSE TO DECISION ON REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Dear Sir:

This Request is submitted in response to the Decision on Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d) ("Decision") mailed August 30, 2010 in regard to the above-identified patent ("'080 patent").

Patentee believe that no fees are required for entry and consideration of this response because it is filed within the one-month period of reply set forth in the Decision, but should any fees be necessary, the U.S. Patent and Trademark Office ("USPTO") is authorized to charge such fees to **Deposit Account No. 50–0206**.

A. Grounds for Request for Reconsideration of Decision

The Decision dismissed the Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d) ("Petition") filed August 13, 2010 because the U.S. Patent and Trademark Office ("USPTO") based the start date of the "B period" of the Patent Term Adjustment ("PTA") on a national stage commencement 371(f) date of October 2, 2009, not the filing date of September 29, 2006.

Patentee requests that the Decision be reconsidered in view of the Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage pursuant to 35 U.S.C. § 371 of September 9, 2009 ("Notice"), submitted herewith as **Exhibit A**, and the following discussion of the calculation of the B period.

B. Calculation of PTA under 37 C.F.R. § 1.703

The following facts are relevant for determining PTA for the '080 patent.

- March 31, 2004 — date U.S. Provisional Patent Application No. 60/557,708 was filed (earliest priority date of the '080 patent). *See* **Exhibit B** (Cover Sheet of Certified Copy).
- September 29, 2006 — date U.S. Patent Application No. 10/594,969 was filed. *See* **Exhibit C** (Transmittal Sheet with USPTO date stamp).
- September 30, 2006 — date national stage commenced under 35 U.S.C. § 371(b) ("371(b) date").[1]
- September 30, 2009 — three years from the national stage commencement date under 35 U.S.C. § 371(b) (*i.e.*, beginning of "B period").
- June 22, 2010 — U.S. Patent No. 7,741,080 issues (*i.e.*, end of "B period").

[1] This is in contrast with the 371(b) date of October 2, 2009 asserted in the Decision.

C. Decision used in incorrect national stage completion date.

The USPTO stated that the national stage completion date under 35 U.S.C. § 371(f) of October 2, 2009 must be used to calculate the start date of the B period, not September 29, 2009, three years from the filing date of the '080 patent.[2] Patentee respectfully requests reconsideration of this date.

35 U.S.C. § 154(1)(b)(B) clearly states that, "the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States," not the national stage completion date.[3] Further, the USPTO stated that the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) is measured from the date that the national stage commences under 35 U.S.C. § 371(b) or (f) in an international patent application.[4] Under 35 U.S.C. § 371(b), the national stage commences 30 months from the earliest priority date of the international patent application, unless Applicant satisfies the requirements of 35 U.S.C. § 371(c) and expressly requests early processing prior to the thirty-month date.

35 U.S.C. § 371(f) relates to a situation where an Applicant satisfies the requirements of 35 U.S.C. § 371(c) and files an express request for early processing of a patent application. In the absence of filing such a request, the national stage commences under 35 U.S.C. § 371(b) (*i.e.*, with the expiration of the applicable time limit under Article 22(1) or (2), or under Article 39(1) of the Patent Cooperation Treaty).[5]

Although Patentee expressly requested early processing prior the thirty-month date, Patentee did not include Item (9), a copy of the oath or declaration of the inventors as filed in the PCT Request as required by the USPTO.[6] Thus, the '080 patent did not satisfy the requirements of 35 U.S.C. § 371(f). In a situation where a patent has a 371(b) but not a 371(f) date, the USPTO has taken the position that the 371(b) date is used to calculate the B period in U.S. Patent No. 7,465,444 ("Japan Tobacco").[7] Patentee

---

[2] Decision, page 1.
[3] Emphasis added.
[4] *See* Notice of September 9, 2009 (**Exhibit A**).
[5] *See* 35 U.S.C. § 351(a).
[6] *See* **Exhibit B**; *See also* 35 U.S.C. § 371(c)(4).
[7] *See* **Exhibit D.**

respectfully requests similar treatment and submits that the "actual filing date" of the '080 patent, for purposes of calculating the B period under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the 371(b) date.

D. "B" Periods Under 37 C.F.R. § 1.702(b)

The '080 patent issued from U.S. Patent Application No. 10/594,969, which is a national stage filing under 35 U.S.C. § 371 of International Patent Application No. PCT/JP2005/06357, filed March 31, 2005, which claims benefit of U.S. Provisional Patent Application No. 60/557,708.

The national stage for the '080 patent commenced under 35 U.S.C. § 371(b), *i.e.*, upon expiration of 30 months from the priority date of the international application.[8] As a result, the date that the national stage commenced was September 30, 2006 (*i.e.*, 30 months from the priority date of March 31, 2004).

The number of days from the beginning of the "B period" (September 30, 2009, *i.e.*, three years from the 371(b) date) to the end of the "B period" (June 22, 2010, *i.e.*, the day the '080 patent issued) is 266 days.

In view of the B period detailed herein, the B period for the '080 patent is 266 days. The USPTO calculated a B period of 263 days.[9] Patentee respectfully submits that the USPTO's calculation of the B period is incorrect and the correct B period is 266 days.

---

[8] The '080 patent did not satisfy 35 U.S.C. § 371(f) when U.S. Patent Application No. 10/594,969 was filed.

[9] *See* Decision, 1.

E. PTA = (A Period + B Period) – Applicants Delay

The PTA should be calculated as follows:

A period = 149 days.[10]

B period = 266 days. *See* Item D above.

Applicants' delay = 127 days.[11]

(149 + 266) – 127 = 288 days

Accordingly, Patentee respectfully requests that the '080 patent be granted a minimum PTA of at least **288 days**. Patentee respectfully submits that the conditions for grant of the Petition under 37 C.F.R. § 1.705(d) have been met, the Petition should be granted, and the PTA corrected to 288 days.

[10] Patentee accepts the USPTO's calculation of the A period. *See* Decision.
[11] Patentee accepts the USPTO's calculation of Applicant's delay. *See* Decision.

CONCLUSION

In view of the above remarks, it is respectfully requested that this Request for Reconsideration of Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of at least **288 days**.

Respectfully submitted,
HUNTON & WILLIAMS LLP

Date: 9/30/2010

By: _____
Laurence H. Posorske, Ph.D.
Registration No. 34,698

Christopher J. Nichols, Ph.D.
Registration No. 55,984

HUNTON & WILLIAMS LLP
Intellectual Property Department
1900 K Street, N.W., Suite 1200
Washington, D.C. 20006
(202) 955–1500 (telephone)
(202) 778–2201 (facsimile)

Exhibit A

Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage pursuant to 35 U.S.C. § 371 of September 9, 2009

Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C § 371

Summary: The computer program that the United States Patent and Trademark Office (USPTO) uses to calculate patent term adjustment incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications if the requirements of 35 U.S.C. § 371 are not fulfilled on the date that the national stage commenced under 35 U.S.C. § 371(b) or (f). The USPTO is in the process of correcting this computer program. Applicants seeking a revised patent term adjustment determination based on this calculation must submit a timely request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d).

Background: Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional patent term adjustment if the issue of an original patent is delayed due to the failure of the USPTO to issue a patent within three years after the actual filing date of the application. The USPTO implemented the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) in 37 CFR 1.702(b) and 37 CFR 1.703(b). See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56365, 56391-92 (Sept. 18, 2000) (final rule). The USPTO indicated the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) is measured from the date that the national stage commences under 35 U.S C. § 371(b) or (f) in an international application. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. at 56382-84.

The USPTO makes patent term adjustment determinations by a computer program that uses the information recorded in the USPTO's automated patent application information system (the Patent Application Locating and Monitoring system or PALM system), except when an applicant requests reconsideration pursuant to 37 CFR 1.705. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. at 56370, 56380-81.

Discussion: The USPTO is in the process of correcting an error in the computer program that it uses to calculate the patent term adjustment that affects patents issuing from international applications entering the national stage as to the United States pursuant to 35 U.S.C. § 371. The USPTO's computer program incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications as being measured from the date that the requirements of 35 U.S.C. § 371 were fulfilled rather than the date the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application. The USPTO is correcting the computer program to reflect that the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications is measured from the date the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application.

An applicant seeking a revised patent term adjustment determination based upon the three-year pendency provision must submit a timely request for reconsideration of the patent term adjustment indicated in the patent. The USPTO does not calculate and inform the applicant of the patent term adjustment based upon the three-year pendency

provision of 35 U.S.C. § 154(b)(1)(B) in the notice of allowance because the USPTO must know the date the patent will issue to be able to calculate the patent term adjustment based upon this provision. Thus, reconsideration of the patent term adjustment indicated in the patent as it relates to the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) is **not** considered a matter that could have been raised in an application for patent term adjustment under 37 CFR 1.705(b) (provides for reconsideration of the patent term adjustment indicated in the notice of allowance). Therefore, a request for reconsideration of the patent term adjustment calculation based on the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) will be considered timely under 37 CFR 1.705(d) if filed within two months of the date the patent issued.

For Further Information Contact: The Office of Patent Legal Administration by telephone at (571) 272-7702, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: 9/9/09

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Exhibit B

Cover Sheet of Certified Copy U.S. Provisional Patent Application No. 60/557,708

PCT/JP2005/006357

22. 4. 2005

PA 1305178

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

April 12, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: *60/557,708*
FILING DATE: *March 31, 2004*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

P. R. GRANT
Certifying Officer

Exhibit C
Transmittal Sheet with USPTO date stamp

PTO-1390 (Rev. 07-2005) (modified)

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371	ATTORNEY'S DOCKET NUMBER: 68600.000002
	U.S. APPLICATION NO. (if known, see 37 CFR 1.5): Unassigned 10/594969

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/JP2005/006357	March 31, 2005	March 31, 2004

TITLE OF INVENTION

ADIPONECTIN EXPRESSION-INDUCING AGENTS AND USES THEREOF

APPLICANT(S) FOR DO/EO/US

Takashi KADOWAKI Toshimasa YAMAUCHI Shoko KITAJIMA Yusuke ITO

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☒ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☒ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ A copy of the oath or declaration of the inventor(s) as filed in the PCT Request (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A Preliminary Amendment.
14. ☒ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.7)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
Unassigned 10/594969	PCT/JP2005/006357	68600.000002

The following fees have been submitted:	CALCULATIONS	PTO USE
21. ☒ **Basic National Fee (37 CFR 1.492(a))** **$ 300.00**	$ 300.00	
22. ☒ **Examination Fee (37 CFR 1.492(c))**		
If the written opinion prepared by ISA/US or the International Preliminary Examination Report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) **$ 0.00**	$ 200.00	
All other situations **$ 200.00**		
23. ☒ **Search Fee (37 CFR 1.492(b))**		
If the written opinion of the ISA/US or the International Preliminary Examination Report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) **$ 0.00**		
Search Fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority **$ 100.00**	$ 400.00	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB **$ 400.00**		
All other situations **$ 500.00**		
TOTAL OF ABOVE CALCULATIONS = $	$ 900.00	
☒ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing filed in an electronic medium) (37 CFR 1.492(j)). The fee is **$250.00** for each additional 50 sheets of paper or fraction		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round **up** to a whole number)	RATE		
41- 100	0 /50	0	x **$250.00**	$ 0.00	
Surcharge of **$130.00** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h))				$	

CLAIMS	NUMBER FILED	NUMBER EXTRA		RATE		
Total claims	11 - 20 =	0	x	$ 50.00	$ 0.00	
Independent claims	3 - 3 =	0	x	$200.00	$ 0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+	$360.00	$ 360.00	
TOTAL OF ABOVE CALCULATIONS =					$ 1260.00	
☐ Applicant claims small entity status. See 37 CFR 1.27. The fees above are reduced by 1/2.					$	
SUBTOTAL =					$ 1260.00	
Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +					$	
TOTAL NATIONAL FEE =					$ 1260.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +					$ 0.00	
TOTAL FEES ENCLOSED =					$ 1260.00	
					Amount to be refunded:	$
					Amount to be charged:	$

IAP2 Rec'd PCT/PTO 29 SEP 2006

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.7)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/594969 Unassigned	PCT/JP2005/006357	68600.000002

a. ☒ A check in the amount of **$1260.00** to cover the above fees is enclosed.

b. ☐ Please charge Deposit Account No. **50-0206** in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit to Deposit Account No. **50-0206** A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING**: Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

CUSTOMER NO. 21967

Intellectual Property Department
Hunton & Williams LLP
1900 K Street, N.W.; Suite 1200
Washington, DC 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

SIGNATURE

Christopher J. Nichols, Ph.D.
NAME

55,984
REGISTRATION NUMBER

DATE September 29, 2006

Exhibit D
Request for Recalculation of Patent Term Adjustment and
Petition Decision from U.S. Patent No. 7,465,444

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Mamoru Watanabe	Art Unit	: 1644
Patent No.	: 7,465,444	Examiner	: Ilia I. Ouspenski
Issue Date	: December 16, 2008	Conf. No.	: 3057
Serial No.	: 10/472,743		
371 date	: March 4, 2004		
Title	: METHODS OF SUPPRESSING OR TREATING AN INFLAMMATORY BOWEL DISEASE BY ADMINISTERING AN ANTIBODY OR PORTION THEREOF THAT BINDS TO AILIM		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 653 to 1,322 days, is respectfully requested.

REMARKS

(1) Measuring Overlap of "A Delay" and "B Delay"

"A Delays" are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (U.S. District Court, D.C., CA No. 07-1492, Mem. Op. September 30, 2008), the only way that these periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

CERTIFICATE OF MAILING BY EFS-WEB FILING

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: January 8, 2009

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." "B delay" begins only after the PTO has failed to issue a patent within three years, not before. Id.

(2) Measuring "B Delay" for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the "overlap" issue addressed above, Patentee respectfully submits that the Office did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). It is Patentee's understanding that for purposes of calculating "B Delay," the Office measured application pendency as beginning on March 4, 2004, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, as detailed below, the relevant statutes and regulations require that when calculating "B Delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application (i.e., not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371).

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the "actual filing date" of the application.

> (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.
> 35 U.S.C. § 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term "actual filing date" as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins

if the Office fails to issue a patent within three years after the date the national stage "commenced under 35 U.S.C. 371(b) or (f)."[1]

> (b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application "commences."

> (b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

> (f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term "the treaty" refers to "the Patent Cooperation Treaty done at Washington, on June 19, 1970." See 35 U.S.C. § 351(a).

---

[1] Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that "[i]n the case of an international application, the phrase 'actual filing date of the application in the United States' [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371(b) or (f)."

The articles of the Patent Cooperation Treaty cited in 35 U.S.C. § 371(b) are reproduced below.

Article 22

Copy, Translation, and Fee, to Designated Offices

(1) The applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date. (emphasis added)

(2) Where the International Searching Authority makes a declaration, under Article 17(2)(a), that no international search report will be established, the time limit for performing the acts referred to in paragraph (1) of this Article shall be the same as that provided for in paragraph (1).

Article 39
Copy, Translation, and Fee, to Elected Offices

(1) (a) If the election of any Contracting State has been effected prior to the expiration of the 19th month from the priority date, the provisions of Article 22 shall not apply to such State and the applicant shall furnish a copy of the international application (unless the communication under Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each elected Office not later than at the expiration of 30 months from the priority date. (emphasis added)

"The applicable time limit" referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is "the expiration of 30 months from the priority date." As a result, "the expiration of 30 months from the priority date" is the time at which the U.S. national stage commences

under the provisions of 35 U.S.C. § 371(b). This same conclusion as to the timing for commencement of the U.S. national stage is also summarized in MPEP § 1893.01.

> Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(f) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c). MPEP § 1893.01. (emphasis added)

In view of the foregoing, the "actual filing date" of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B Delay" under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application.[2]

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

"A Delay"

A first PTO action was due on or before May 4, 2005 (the date that is fourteen months after March 4, 2004, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first non-final Office Action on October 24, 2006, thereby according a PTO Delay of 538 days. Patentee does not dispute the PTO's calculation for this "A Delay" from May 5, 2005 (the day after the date that is fourteen months after the date on

[2] In contrast to reliance on "the expiration of 30 months from the priority date" for measuring "B Delay," the beginning of the relevant period for purposes of calculating "A Delay" is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II)and 37 C.F.R. § 1.702(a)(1).

which the application fulfilled the requirements of 35 U.S.C. § 371), to October 24, 2006. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of "A Delay" detailed above, the total "A Delay" for this patent should be calculated as 538 days.

"B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/JP02/01361, filed February 18, 2002, which claims the benefit of priority of Japanese application number 2001-89158, filed March 27, 2001, and Japanese application number 2002-19291, filed January 29, 2002.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(b), i.e., upon expiration of 30 months from the priority date of the international application.[3] As a result, the date that the national stage commenced was September 27, 2003 (i.e., 30 months from the priority date of March 27, 2001).

The period beginning on September 28, 2006 (the day after the date that is three years after September 27, 2003, the date that the national stage commenced), and ending December 16, 2008 (the date the patent was issued), is 811 days in length.

In view of the period of "B Delay" detailed above, the total "B Delay" for this patent should be calculated as 811 days. The PTO calculated 115 days of delay for issuance of a patent more than three years after filing. Patentee respectfully submits that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 811 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

[3] No request for early processing under 35 U.S.C. § 371(f) was filed for the present application.

Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period:

May 5, 2005, to October 24, 2006.

As detailed above, "B Delay" accumulated during the following period:

September 28, 2006, to December 16, 2008.

The "A Delay" and the "B Delay" overlap (i.e., occur on the same calendar day) for a total of 27 days, from September 28, 2006, to October 24, 2006.

Applicant Delay

There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth 37 C.F.R. § 1.704.

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Patentee believes the PTA calculation of 653 days is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

1) Total PTO Delay should be calculated as 1,322 days (i.e., the sum of 538 days of "A Delay" and 811 days of "B Delay" minus the 27 days of overlap);

2) Total Applicant Delay should be calculated as 0 days; and

3) Total PTA should be calculated as 1,322 days.

Please apply the fee of $200 required under 37 C.F.R. § 1.18(e) and any other required charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket Number 14539-0010US1.

Respectfully submitted,

Date: January 8, 2009

Jack Brennan
Reg. No. 47,443

Fish & Richardson P.C.
Citigroup Center
52nd Floor
153 East 53rd Street
New York, New York 10022-4611
Telephone: (212) 765-5070
Facsimile: (877) 769-7945

30464624.doc

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

FISH & RICHARDSON P.C.
P.O. BOX 1022
MINNEAPOLIS MN 55440-1022

COPY MAILED

JUN 16 2009

OFFICE OF PETITIONS

In re Patent No. 7,465,444 :
Mamoru Watanabe :
Issue Date: December 16, 2008 :
Application No. 10/472,743 : DECISION ON REQUEST FOR
Filed: March 24, 2004 : RECONSIDERATION OF
Attorney Docket No. 14539-010US1 : PATENT TERM ADJUSTMENT
Title: Methods Of Suppressing or Treating An Inflammatory Bowel Disease by Administering an Antibody or Portion Thereof That Binds To Ailim :

This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)," filed January 8, 2009.

The application for reconsideration of patent term adjustment is **GRANTED** to the extent indicated herein.

The above-identified application matured into U.S. Patent No. 7,465,444 on December 16, 2008. The patent issued with a patent term adjustment of 653 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See, 37 CFR 1.705(d). Patentees request that the patent term adjustment determination for the above-identified patent be changed from 653 days to 1322 days.

Patentee requests recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under 35 U.S.C. 154(b)(1)(A) overlaps with a delay under 35 U.S.C. 154(b)(1)(B) only if the delays occur on the same day.

The petition submitted by patentee sets forth a period of adjustment for Office delays totaling 1349 days (Three Year Delay under 37 CFR 1.703(b) of 811 days *plus* a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a) of 538 days). The petition also sets forth an overlap of 27 days. The petition reflects a reduction of patent term adjustment totaling "0" days for applicant's failure to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. Thus, patentee asserts entitlement to an overall adjustment of 1322 days (1349(811+538)) days for Office delay *less* 27 days for overlap).

Patentee's petition does not dispute the adjustments under 37 CFR 1.702(a) totaling 538 days. Patentee's petition acknowledges the "0" reductions for applicant's failure to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. These reductions total 0 days.

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704.

The Office agrees that as of the issuance of the patent on December 16, 2008, the application was pending three years and 811 days after the commencement date (September 27, 2003) pursuant to 37 CFR 1.371.The Office agrees that because certain actions were not taken within specified time frames, the patent is entitled to an adjustment of 538 days pursuant to 37 CFR 1.702(a). At issue is whether patentees should accrue an additional 811 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 538 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 538 of the 811 days overlap. Patentee's calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

> To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the

patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

> To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

> If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application or the national stage commenced under 35 U.S.C. 371(b) or (f), is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing or commencement date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See, 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See, Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See, also, Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See, also, Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application or the national stage commenced under 35 U.S.C. 371(b) or (f), is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

> Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the

actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718[1]

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application commenced overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the commencement date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office

The application actually issued three years and 811 days after its commencement date. The Office did not delay 538 days and then delay an additional 811 days.

Accordingly, the proper adjustment of 811 days of patent term adjustment (not 538 days and 811 days) should have been entered because the period of delay of 538 of 811 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 538 days attributable to grounds specified in § 1.702(a). Entry of both periods is not warranted. Thus, 811 days is determined to be the actual number of days that the issuance of the patent was delayed.

In view thereof, the patent term adjustment indicated in the patent should have been eight hundred eleven (811) days.

Receipt of the $200.00 fee set forth in 37 CFR 1.18(e) is acknowledged. No additional fees are required.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond to

---

[1] The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

this decision. No extensions of time will be granted under § 1.136.

The application will be forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. See 35 U.S.C. § 254 and 37 CFR§ 1.322. After the thirty day time period has elapsed, the Office will sua sponte issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by eight hundred eleven **(811)** days.

Kery A. Fries

Kery Fries
Senior Legal Advisor Attorney
Office of Patent Legal Administration

Cc: Fish & Richardson P.C.
Citigroup Center
52nd Floor
153 East 53rd Street
New York, NY 10022-4611